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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,201	09/25/2001	Steven J. Brown	AXIOM.016A	2903

7590 10/05/2005

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EXAMINER	
GARVEY, TARA L	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,201	BROWN ET AL.	
	Examiner	Art Unit	
	Tara L Garvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-13 and 26-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 26-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Claims 1-13 and 26-40 are pending. Claims 14-25 and 41-42 are cancelled. The receipt of the substituted claim amendments in reply to the Notice of Non-compliant Amendment on June 23, 2005 is acknowledged.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Applicants' arguments filed on March 4, 2004 have been fully considered. Applicant argue that the remaining references do not teach all the limitations of the claims when Lorens et al is removed as a viable reference.

The declaration filed on March 4, 2005 under 37 CFR §1.131 has been considered but is ineffective to overcome the Lorens et al reference. The declaration is not proper since the signature of all inventors involved in the rejected claims is not present on the declaration, but would otherwise be convincing. At this time, Lorens et al remains a viable reference.

Claims 1-10, 12 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lorens et al (US 2004/0002056 of which the effective date is May 10, 2001) in view of Case et (US 6,780,590) and in further view of Grissmer et al (Molecular

Pharmacology, 1995, volume 45, pages 1227-1234) for reasons as set forth in the office action mailed on October 6, 2004.

The rejection of claims 14-25 under 35 U.S.C. 103(a) as being unpatentable over over Uchino et al. in view of Renard et al. and further in view of Grissmer et al. is withdrawn due to the cancellation of the claims.

The rejection of claims 41-42 under 35 U.S.C. 103(a) as being unpatentable over over Uchino et al. in view of Choi et al. and further in view of Grissmer et al. is withdrawn due to the cancellation of the claims.

Claim Objections

Claim 11 remains objected to as being dependent upon a rejected base claim due to the reasons stated previously for the maintained rejection of claims 1-10, 12 and 13.

Claims 26-40 were not dependent on claim 1 and therefore the declaration under 37 C.F.R. §1.131 will not overcome these objections.

New Grounds of Rejection

Claim Objections

Claims 26-40 are objected to because of the following informalities: These claims are dependent on cancelled claim 25. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of the claims cannot be determined since the claims are dependent on a cancelled claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 9-10 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino et al (Molecular Brain Research, 1997, volume 44, pages 1-11) in view of Case et al (US 6,780,590).

Uchino et al teach a drug screening assay in which the NMDA channel receptor protein is expressed in CHO cells under the control of the inducible hsp70 promoter, the levels of the current were measured with and without induction of NMDA expression, test antagonistic compounds were added to the system and the Ca2+ levels were measured in response to the compounds added (abstract; page 2, left column, second paragraph; page 4, right column, third paragraph bridging page 6, left column; page 7, left column, second paragraph bridging page 8, right column).

Uchino does not teach repeating the contacting step with additional compounds. Case et al teaches that after the initial compound that addition compounds can be tested in a screening assay (column 45, lines 62-66).

It would have been obvious to modify the teachings of Uchino et al to screen multiple compounds that modulate a target protein during one experiment because Uchino et al teach the contacting of a compound with a cell followed by the

measurement of a parameter such as Ca2+ levels and because Case et al teaches that the screening can be repeated with additional compounds. One would have been motivated to do so in order to receive the expected benefit, as suggested by Uchino et al and exemplified by Case et al, of using a drug screening system for identifying drugs that modulate the activity of a target protein multiple times once the expression of the target protein has been induced. Absent of any evidence to the contrary, there would have been a reasonable expectation of success in screening multiple drugs once the expression of the target protein was induced since the system was already known to be functional from the first compound.

Claims 1-10 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino et al (Molecular Brain Research, 1997, volume 44, pages 1-11) in view of Case et al (US 6,780,590) and in further view of Renard et al (European Journal of Pharmacology, 1999, volume 366, pages 319-328).

Uchino et al and Case et al have been described previously.

Uchino et al and Case et al do not teach the promoter being induced with an inducer molecule or by removal or inhibition of a repressor. Renard et al teaches a stable cell line expressing the NMDA receptor subunits under the control of a tetracycline inducible promoter in HEK293 cells (abstract; page 321 right column, fourth paragraph bridging page 323, left column, first paragraph).

It would have been obvious to one of ordinary skill in the art to modify the teachings of Uchino to use tetracycline to control the expression of a potassium ion

channel in a stable cell line for drug screening because Uchino et al teach that it is within the skill of the art to use an inducible promoter to control the expression of an ion channel target in a system to screen drugs and Case et al and Renard et al teach that multiple compounds can be tested and a tetracycline inducible promoter system can be used to induce the expression of a target protein in a drug screening system.

One would have been motivated to do so in order to receive the expected benefit, as suggested by Uchino et al and actually exemplified by Case et al and Renard et al, of using a system that to screen multiple compounds that modulate a test protein such as an ion channel protein in which the expression of the target protein is controlled by an inducer molecule such as tetracycline. Absent of any evidence to the contrary, there would have been reasonable expectation of success in using a system of tetracycline controlled expression of an target protein in the stable cell to screen for multiple potential drugs since tetracycline has been successfully used as an inducible expression system for many genes.

Claims 1-6, 11 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino et al (Molecular Brain Research, 1997, volume 44, pages 1-11) in view of Case et al (US 6,780,590) and in further view of Renard et al (European Journal of Pharmacology, 1999, volume 366, pages 319-328).

Uchino et al and Case et al have been described previously.

Uchino et al and Case et al do not teach a second cell line expressing a reporter under the control of an inducible reporter to test the effect of an identified test

compound. Renard et al teaches an inducible promoter controlling the expression of a reporter gene and the use of a reporter such as mAequorin to measure the effect of an identified test compound on a reporter (abstract, page 320, right column, page 321, right column, pages 324 left column, last paragraph bridging right column bridging page 325, page 326, right column, last paragraph bridging page 327).

It would have been obvious to modify the teachings of Uchino et al to screen multiple compounds that modulate a target protein during one experiment and to screen the identified compound against a reporter because Uchino et al teach the contacting of a compound with a cell followed by the measurement of a parameter such as Ca2+ levels and because Case et al and Renard et al teach that the initial screening can be repeated with additional compounds and that the identified compounds can be screened against a reporter. One would have been motivated to do so in order to receive the expected benefit, as suggested by Uchino et al and exemplified by Case et al and Renard et al, of using a screening system to identify multiple compounds that modulate the activity of a target protein and to further test the functional ability of these compounds against a reporter. Absent of any evidence to the contrary, there would have been a reasonable expectation of success in screening multiple drugs once the expression of the target protein was induced since the system was already known to be functional from the first compound and in determining the function of a test compound since functional reporter have been used successfully to determine the function of a compound.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara L Garvey whose telephone number is (571) 272-2917. The examiner can normally be reached on Monday through Friday 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tara L Garvey
Examiner
Art Unit 1636

TLG

JAMES KETTER
PRIMARY EXAMINER